K010135

FEB 1 6 2001

510(k) SUMMARY
INVACARE CORPORATION'S
510(k) PREMARKET NOTIFICATION
MODELS LYNX AND PANTHER MOTORIZED SCOOTERS

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Contact Person: Rae Ann Farrow
Manager, Regulatory Compliance

Date Prepared: January 15, 2001

Name of Device and Name/Address of Sponsor:

Models Lynx and Panther Motorized Scooters with DS2000 controller. This is a modification to the Lynx and Panther Motorized Scooters with the Solo 60 controller previously cleared by K992052 on 8/12/99.

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 366-9724

Common or Usual Name

Scooter

Classification Name

Motorized Three Wheel Vehicle

Predicate Devices

The Model Lynx and Panther Scooters with the DS2000 controller are substantially equivalent to the Lynx and Panther scooters with the Solo 60 controller (K992052, 8/12/99),

Intended Use

The intended use of the Lynx and Panther scooters is to provide mobility to persons limited to a seated position.

Technological Characteristics and Substantial Equivalence

Device Description

The Lynx and Panther motorized scooters with the DS2000 Controller are modifications of the previously cleared "Lynx" and "Panther" motorized scooters (K992052, 8/12/99), with the modified version utilizing the **Dynamic Controls Limited DS2000** controller rather than the **Penny & Giles Drives Technologies Ltd. Solo 60** controller. The intended function and use of the scooters has not changed.

Substantial Equivalence

The Invacare Models Lynx and Panther Series scooters with the DS2000 controller are a modification to the to the Lynx and Panther scooters with the Solo 60 controller (K992052, 8/12/99) and are therefore substantially equivalent. The modification includes changing the controller model to the Dynamic Controls DS2000 controller from the Penny & Giles Solo 60 controller. The scooters with the DS2000 controller have the same intended use as the previously cleared devices.

While there are minor differences in performance specifications of the scooters, these differences do not alter the intended function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness. Therefore, Invacare believes that the Lynx and Panther scooters with the DS2000 controller are substantially equivalent to legally marketed devices currently in commercial distribution.

Performance Data

The Invacare Models Lynx and Panther scooters meet the applicable requirements specified in the Rehabilitation Engineering Society of North America (RESNA) Standard ANSI/RESNA WC/14 (1991) and ISO Standard ISO 7176: 1993 (E) "ISO Standard, Wheelchairs - Requirements and Test Methods for the Power and Control Systems of Electric Wheelchairs .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 6 2001

Ms. Rae Ann Farrow
Manager, Regulatory Compliance
Invacare Corporation
One Invacare Way
P.O. Box 4028
Elyria, Ohio 44036

Re: K010135
Trade Name: Models Lynx and Panther Motorized Scooters, Models Lynx SX-3, Lynx
Regulatory Class: II
Product Code: INI
Dated: January 15, 2001
Received: January 17, 2001

Dear Ms. Farrow:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): *K010135*

Device Name: *Invacare Models Lynx and Panther Motorized Scooters with DS2000 Controller*

Indications For Use:

The intended use of the Invacare Models Lynx and Panther Motorized Scooters with DS2000 Controller is to provide mobility to persons limited to a seated position.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

for Mark N. Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010135

(Optional Format 1-2-96)